

## REMARKS

The above-identified patent application is the United States national stage of international PCT Patent Application No. PCT/US00/26870. The United States was designated as the International Search Authority and as the International Preliminary Examining Authority. The original PCT application included claims 1-202 each satisfying the criteria of PCT Article 33(1)-(4) as to novelty, inventive step and industrial applicability. The applicant has amended claims 67, 69, 70, 76, 81, 88, 118, 119, 120, 122, 126, 160, 165, 182, 183, and 190 in the application only to the extent necessary to eliminate objections as to form. The applicant has without prejudice cancelled claims 1-41 which were the subject matter of United States Application No. 09/408,584. The applicant has further canceled claims 201 and 202 to eliminate any objection as to form. The applicant respectfully requests examination of remaining claims 42-200.

When all the claims in an PCT application satisfy each of the criteria of PCT Article 33(1)-(4) and when the applicant only amends the claims to the extent necessary to eliminate objections as to form or to cancel rejected claims the applicant may pay the fee set forth in 37 C.F.R. §1.492(a)(4) and request that the application be taken out of order pursuant to 37 C.F. R. §1.496(b). As such, the applicant has paid the fee as set forth in 37 C.F.R. §1.492(a)(4) and the applicant respectfully requests that this application be taken out of order for examination.

The application was considered to have met the requirement of unity of invention throughout the international search and the international examination and no invitation to pay additional fees was made under Article 17 (3)(a). During the national stage of a PCT application when considering unity of invention of claims under 35 U.S.C. §§121, 371, and 372; Rule 13.1 and 13.2 will be followed without regard to the practice in national applications filed under 35 U.S.C. 111 and §1850 MPEP. Unity of invention is present when there is a "technical relationship" among the claimed inventions involving one or more of the same or corresponding "special technical features". Rule 13.2 PCT. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Rule 13.2 PCT. Moreover, the rules specifically allow for inventions within the same application

when there is a relationship between a product, process, and use §1850 C (A). Illustrations of Particular Situations.

In the original application, an unusually large number of claims were presented in order to adequately claim the various aspects of the present invention(s) in dependent and alternatively independent fashions. The applicant has voluntarily reduced the number of claims by cancellation of claims 1-41 and 201-202 as filed in the original application, leaving only claims 42-200 for examination, including several closely related independent claims having unity of invention along with their dependent claims.

Thus, the applicants have voluntarily reduced the number of claims to assist the examiners in their efforts and to expedite the examination. The voluntary reduction in claim number is not to be construed as a waiver of any right to file other applications such as continuations, divisions, continuations-in-part, or similar applications and have the remaining claims examined without any reduction in breadth. The applicant respectfully requests that each of claims 42-200 be examined as single group as part of this United States National Stage application.

The applicant has set out a clean version of the claims above and a version with markings to show changes made pursuant to 37 C.F.R. §1.121 beginning on the next separate. The applicant respectfully requests allowance of the claims at the examiner's earliest convenience.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 1-41 Cancelled without prejudice.

42. A kit for intranasal delivery, comprising:
- a. a dose;
  - b. a diluent in which said dose may be combined; and
  - c. an intranasal device comprising:
    - i. an intranasal probe having a dose delivery aperture;
    - ii. a dose administrator having a first end and a second end, wherein said first end is responsive to said intranasal probe; and
    - iii. an intranasal probe coupler responsive to said intranasal probe and said first end of said dose administrator, wherein said intranasal probe coupler has at least one aperture which communicates between said dose administrator and said intranasal probe.
43. An intranasal delivery device as described in claim 42, further comprising a force application element coupled to said second end of said flexible dose administrator.
44. An intranasal delivery device as described in claim 42, wherein said dose comprises a material selected from the group consisting of: an equine cold-adapted live influenza virus which replicates in embryonated chicken eggs within a temperature range from about 26EC to about 30EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 37EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 39EC, a equine cold-adapted live virus having a phenotype wherein protein synthesis is inhibited above about 39EC, an equine cold-adapted live virus having a dominant interference phenotype, an equine influenza cold-adapted live virus derived from strain A/equine/Kentucky/1/91 (H3N8), EIV-P821(identified by accession No. ATCC VR 2625), EIV-P824 (identified by accession No. ATCC VR 2624), MSV+5 (identified by

accession No.2627), any progeny of any of said equine influenza viruses identified by such accession Nos., any EIV having the identifying characteristics of said ATCC VR strains, or an equine influenza cold adapted live virus having about  $10^5$  TCID<sub>50</sub> to about  $10^8$  TCID<sub>50</sub> units.

45. An equine intranasal delivery device as described in claim 43, wherein said force application element is a syringe.
46. An intranasal delivery device as described in claim 45, wherein said dose administrator comprises a flexible material.
47. An intranasal delivery device as described in claim 42, further comprising a dose-location coordinate indicator responsive to said flexible dose administrator.
48. An equine intranasal delivery device as described in claim 47, wherein said dose-location coordinate indicator has a position which assures a dose-location coordinate temperature between about  $26^{\circ}\text{C}$  to about  $34^{\circ}\text{C}$ .
49. An intranasal delivery device as described in claim 42, further comprising a force dissemination contact surface having hebetated termini responsive to said exterior surface of said intranasal probe.
50. An intranasal delivery device as described in claim 42, further comprising a conformable dose sequestration element having a dose sequestration volume sufficient to sequester said dose.
51. An intranasal delivery device as described in claim 50, wherein said conformable dose sequestration element further comprises a dose retainer, wherein said dose retainer positions said dose proximate to said dose delivery aperture.
52. An intranasal delivery device as described in claim 42, further comprising a stream

delivery element coupled to said dose delivery aperture.

53. An equine intranasal delivery device, comprising:
- a. a dose administrator;
  - b. a force application element coupled to said dose administrator; and
  - c. an equine influenza cold-adapted live virus derived from strain A/equine/Kentucky/1/91 (H3N8), EIV-P821 (identified by accession No. ATCC VR 2625), EIV-P824 (identified by accession No. ATCC VR 2624), MSV+5 (identified by accession No. 2627) dose responsive to said force application element.
54. An equine intranasal delivery device as described in claim 53, further comprising a dose diluent, wherein said dose and said dose diluent are combined.
55. An equine intranasal delivery device as described in claim 54, wherein said force application element is a syringe.
56. An equine intranasal delivery device as described in claim 55, further comprising a coupler element having a first end responsive to said dose administrator and a second end responsive to said force application element, wherein said coupler element has at least one aperture which communicates between a volume of said dose administrator and said force application element.
57. An equine intranasal delivery device as described in claim 56, further comprising an intranasal probe coupled to said dose administrator.
58. An equine intranasal delivery device as described in claim 57, further comprising an intranasal probe coupler having a first end responsive to said intranasal probe and a second end responsive to said dose administrator, wherein said intranasal probe coupler has at least one aperture which communicates between said volume of said dose administrator and an exterior surface of said intranasal probe.

59. An equine intranasal delivery device as described in claim 58, wherein said dose administrator comprises a flexible material.
60. An intranasal delivery device, comprising:
- a. a dose administrator;
  - b. a force application element coupled to said dose administrator; and
  - c. a dose responsive to said force application element.
61. An intranasal delivery device as described in claim 60, further comprising a dose diluent, wherein said dose and said dose diluent are combined.
62. An intranasal delivery device as described in claim 61, wherein said force application element is a syringe.
63. An intranasal delivery device as described in claim 62, further comprising a coupler element having a first end responsive to said dose administrator and a second end responsive to said force application element, wherein said coupler element has at least one aperture which communicates between a volume of said dose administrator and said force application element.
64. An intranasal delivery device as described in claim 63, further comprising an intranasal probe coupled to said dose administrator.
65. An intranasal delivery device as described in claim 64, further comprising an intranasal probe coupler having a first end responsive to said intranasal probe and a second end responsive to said dose administrator, wherein said intranasal probe coupler has at least one aperture which communicates between said volume of said dose administrator and an exterior surface of said intranasal probe.
66. An intranasal delivery device as described in claim 65, wherein said dose

administrator comprises a flexible material.

67. An intranasal delivery device as described in [any one of] claim[s] 60, wherein said dose comprises a material selected from the group consisting of: an equine cold-adapted live influenza virus which replicates in embryonated chicken eggs within a temperature range from about 26EC to about 30EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 37EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 39EC, a equine cold-adapted live virus having a phenotype wherein protein synthesis is inhibited above about 39EC, an equine cold-adapted live virus having a dominant interference phenotype, an equine influenza cold-adapted live virus derived from strain A/equine/ Kentucky/1/91 (H3N8), EIV-P821(identified by accession No. ATCC VR 2625), EIV-P824 (identified by accession No. ATCC VR 2624), MSV+5 (identified by accession No. 2627), any progeny of any of said equine influenza viruses identified by such accession Nos., any EIV having the identifying characteristics of said ATCC VR strains, or an equine influenza cold adapted live virus having about  $10^5$  TCID<sub>50</sub> to about  $10^8$  TCID<sub>50</sub> units.
68. A method for producing an equine intranasal delivery device, comprising the steps of:
- providing a dose delivery aperture element;
  - coupling an intranasal probe to said dose delivery aperture;
  - joining a flexible dose administrator having a first end and a second end to said intranasal probe by said first end; and
  - coupling a conformable dose sequestration element having a dose sequestration volume which communicates with said dose delivery aperture element.
69. A method for producing an equine intranasal delivery device as described in claim 68, further comprising the step of coupling a force application element to said fluid

dose [propellant] propellant.

70. A method for producing an equine intranasal delivery device as described in claim 69, further comprising the step of separating said conformable dose sequestration element having a dose sequestration volume from said force application element with a fluid dose [propellant] propellant.
71. A method for producing an equine intranasal delivery device as described in claim 60, further comprising the step of coupling a force dissemination contact surface having hebetated termini to said intranasal probe.
72. A method for producing an equine intranasal delivery device as described in claim 61, further comprising the step of providing a stream delivery element.
73. A method for producing an equine intranasal delivery device as described in claim 62, further comprising the step of positioning a dose-location coordinate indicator at a location on said flexible dose administrator, wherein said location of said dose-location coordinate indicator assures delivery of said dose to a target which is susceptible to said dose.
74. A method for producing an equine intranasal delivery device as described in claim 73, further comprising the step of joining an axial collapse protection element coupled to said flexible dose administrator.
75. A method for producing an equine intranasal delivery device as described in claim 74, further comprising coupling an intranasal probe coupler to said intranasal probe and to said flexible dose administrator, wherein said intranasal probe coupler has at least one aperture which communicates between said volume of said conformable dose sequestration element and said dose delivery aperture.
76. A method for producing an equine intranasal delivery device as described in claim



75, further comprising the step of coupling a fluid dose [propellent] propellant coupler to said conformable dose sequestration element and to said dose [propellent] propellant, wherein said fluid dose [propellent] propellant coupler has at least one aperture which communicates between said volume of said conformable dose sequestration element and said fluid dose [propellent] propellant.

77. A method for producing an equine intranasal delivery device as described in claim 76, further comprising the step of selecting a dose from the group consisting of: a substance, a composition, a therapeutic composition, a prophylactic composition, a drug, a protein, a nucleic acid, an immunogen, an immunogen which elicits an immune response, a live virus, a reassortant live virus, a cold-adapted live virus, an attenuated live virus, an equine cold-adapted live influenza virus which replicates in embryonated chicken eggs within a temperature range from about 26EC to about 30EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 37EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 39EC, a equine cold-adapted live virus having a phenotype wherein protein synthesis is inhibited above about 39EC, an equine cold-adapted live virus having a dominant interference phenotype, an equine influenza cold-adapted live virus derived from strain A/equine/ Kentucky/1/91 (H3N8), EIV-P821(identified by accession No. ATCC VR2625), EIV-P824 (identified by accession No. ATCC VR2624), MSV+5 (identified by accession No. 2627), any progeny of any of said equine influenza viruses identified by such accession Nos., any EIV having the identifying characteristics of said ATCC VR strains, or an equine influenza cold adapted live virus having about  $10^5$  TCID<sub>50</sub> to about  $10^8$  TCID<sub>50</sub> units.
78. A method for producing an equine intranasal delivery device as described in claim 77, further comprising the step of sequestering a dose within said dose sequestration volume of said conformable dose sequestration element.

79. A method for producing an equine intranasal delivery device as described in claim 78, wherein said step of sequestering said dose within said volume of said conformable dose sequestration element further comprises:
- establishing a volume of diluent containing said dose within said volume of said conformable dose sequestration element;
  - removing said volume of diluent from said dose; and
  - leaving a dry dose within said dose sequestration volume of said conformable dose sequestration element.
80. A method for producing an equine intranasal delivery device as described in claim 78, wherein said step of sequestering said dose within said interior volume of said flexible dose sequestration element further comprises:
- establishing a volume of diluent containing said dose within said volume of said conformable dose sequestration element;
  - establishing conditions within said volume of diluent containing said dose wherein said dose does not substantially degrade.
81. A method of equine intranasal delivery, comprising the steps of:
- sequestering a dose within a conformable dose sequestration element, wherein said conformable dose sequestration element separates said dose from a force application element with a volume of a fluid dose [propellant] propellant;
  - positioning an intranasal probe within a nostril of an equid;
  - sliding said intranasal probe up said nostril of said equid;
  - terminating sliding of said intranasal probe up said nostril;
  - propelling said dose from said conformable dose sequestration element; and
  - delivering said dose onto a target of said equid.
82. A method of intranasal delivery as described in claim 81, wherein said step of delivering said dose onto said target of said equid comprises streaming said dose onto said target of said equid.

83. A method of intranasal delivery as described in claim 82, wherein said step of sequestering a dose within a conformable dose sequestration element, further comprises the steps of:
- establishing at least one dose in a volume of diluent;
  - submerging said dose delivery aperture into said volume of diluent containing at least one dose; and
  - reducing pressure within said conformable dose sequestration element sufficient to transfer said dose established in said volume of diluent into said conformable dose sequestration element.
84. A method of intranasal delivery as described in claim 83, further comprising the step of retaining said dose within said conformable dose sequestration element adjacent to said intranasal probe.
85. A method of intranasal delivery as described in claim 84, further comprising the step of guiding said intranasal probe so as to not enter an opening to a false nostril.
86. A method of intranasal delivery as described in claim 81, further comprising the step of positioning a dose-location coordinate indicator into proximity with an exterior portion of said nostril of said equid.
87. A method of intranasal delivery as described in claim 86, wherein said step of positioning a dose-location coordinate indicator into proximity with an exterior portion of said nostril of said equid assures a dose-location coordinate having a temperature of about 26EC to about 34EC
88. A method of intranasal delivery as described in any one of claims 87, wherein said step of propelling said dose from said conformable dose sequestration element further comprises the steps of:
- measuring a fluid dose [propellent] propellant volume, wherein said volume

of said fluid dose [propellent] propellant is in excess of a volume of a minimum dose delivery volume;

- b. propelling said dose from said volume of said conformable dose sequestration element with a portion of said dose [propellent] propellant volume; and
- c. chasing said dose with a remaining portion of said dose [propellent] propellant volume.

89. An equine intranasal delivery device as described in claim 88, wherein said dose comprises a substance selected from the group consisting of: a substance, a composition, a therapeutic composition, a prophylactic composition, a drug, a protein, a nucleic acid, an immunogen, an immunogen which elicits an immune response, a live virus, a reassortant live virus, a cold-adapted live virus, an attenuated live virus, an equine cold-adapted live influenza virus which replicates in embryonated chicken eggs within a temperature range from about 26EC to about 30EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 37EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 39EC, a equine cold-adapted live virus having a phenotype wherein protein synthesis is inhibited above about 39EC, an equine cold-adapted live virus having a dominant interference phenotype, an equine influenza cold-adapted live virus derived from strain A/equine/ Kentucky/1/91 (H3N8), EIV-P821(identified by accession No. ATCC VR 2625), EIV-P824 (identified by accession No. ATCC VR 2624), MSV+5 (identified by accession No.2627), any progeny of any of said equine influenza viruses identified by such accession Nos., any EIV having the identifying characteristics of said ATCC VR strains, or an equine influenza cold adapted live virus having about  $10^5$  TCID<sub>50</sub> to about  $10^8$  TCID<sub>50</sub> units.

90. An intranasal delivery device, comprising:  
a. a force application element;

- b. a conformable dose sequestration element having a dose sequestration volume sufficiently large to sequester a dose, wherein said conformable dose sequestration element separates said dose from said force application element; and
  - c. a fluid dose [propellent] propellant which separates said conformable dose sequestration element from said force application element.
- 91. An intranasal delivery device as described in claim 90, further comprising an intranasal probe responsive to said conformable dose sequestration element.
- 92. An intranasal delivery device as described in claim 91, further comprising a dose delivery aperture element coupled to said intranasal probe.
- 93. An intranasal delivery device as described in claim 92, further comprising a stream delivery element coupled to said dose delivery aperture element.
- 94. An intranasal delivery device as described in claim 93, wherein said stream delivery element has a diameter of about 0.75 millimeters (about 0.030 inches).
- 95. An intranasal delivery device as described in claim 94, further comprising a flexible dose administrator having a cylindrical exterior surface.
- 96. An intranasal delivery device as described in claim 95, wherein said cylindrical exterior surface of said flexible dose administrator has a radius of 3 millimeters (about 0.125 inches).
- 97. An intranasal delivery device as described in claim 96, wherein said cylindrical exterior surface of said flexible administrator has a length of about 150 millimeters (about 5.9 inches).
- 98. An intranasal delivery device as described in claim 97, further comprising a force

dissemination contact surface having hebetated termini responsive to said intranasal probe.

99. An intranasal delivery device as described in claim 98, wherein said force dissemination contact surface responsive to said intranasal probe comprises a sphere cap wherein said sphere cap and a cylindrical exterior surface of said flexible dose administrator form a contiguous surface.
100. An intranasal delivery device as described in claim 99, wherein said sphere cap has a radius of about 3 millimeters (about 0.125 inches) and a sphere cap height of about 1 millimeters (about 0.040 inches) and wherein said cylindrical exterior surface has a radius of about 3 millimeters (about 0.125 inches).
101. An intranasal delivery device as described in claim 100, wherein said intranasal probe and said force dissemination contact surface have a unitized construction.
102. An intranasal delivery device as described in claim 101, wherein said conformable dose sequestration element further comprises a dose retainer, wherein said dose retainer positions said dose contained within said volume of solvent proximate to said dose delivery aperture.
103. An intranasal delivery device as described in claim 102, wherein said dose retainer is a capillary.
104. An intranasal delivery device as described in claim 103, wherein said capillary has a diameter of about 3 millimeters (about 0.125 inches).
105. An intranasal delivery device as described in claim 104, wherein said volume of diluent is about 1 milliliter.
106. An intranasal delivery device as described in claim 105, wherein said fluid dose

[propellent] propellant has a volume in a range of about 1 milliliters to about 3 milliliters.

107. An intranasal delivery device as described in claim 106, further comprising a dose-location coordinate indicator coupled to said dose sequestration element.
108. An intranasal delivery device as described in claim 107, wherein said dose-location coordinate indicator comprises a visually enhanced surface coupled to said exterior surface of said dose sequestration element.
109. An intranasal delivery device as described in claim 108, wherein said visually enhanced surface coupled to said exterior surface of said dose sequestration element comprises an annular projection.
110. An equine intranasal delivery device as described in claim 119, wherein said dose-location coordinate indicator has a position which assures a dose-location coordinate temperature between about 26<sup>N</sup> C to about 34<sup>N</sup> C.
111. An intranasal delivery device as described in claim 110, wherein said dose-location coordinate indicator has a position at about 150 millimeters (about 5.9 inches) from said first end of said dose sequestration element.
112. An intranasal delivery device as described in claim 111, further comprising an axial collapse prevention element coupled to said dose sequestration element.
113. An intranasal delivery device as described in claim 112, wherein said axial collapse prevention element comprises a flexibly resilient layer between said exterior cylindrical surface of said flexible dose administrator and said volume of said conformable dose sequestration element.
114. An intranasal delivery device as described in claim 113, further comprising an

intranasal probe coupler having a first end responsive to said intranasal probe and a second end responsive to said dose sequestration element, wherein said intranasal probe coupler has at least one aperture which communicates between said volume of said conformable dose sequestration element and said dose delivery aperture.

115. An intranasal delivery device as described in claim 114, wherein said second end of said intranasal probe coupler comprises an annular barb engaged to said interior surface of said conformable dose sequestration element.
116. An intranasal delivery device as described in claim 115, wherein said intranasal probe coupler and intranasal probe comprise unitized construction.
117. An intranasal delivery device as described in claim 116, wherein said intranasal probe coupler, said intranasal probe, and said force dissemination contact surface having hebetated termini comprise unitized construction.
118. An intranasal delivery device as described in claim 117, further comprising a [propellent] propellant coupler having a first end responsive to said interior volume of said dose sequestration element and a second end responsive to said fluid dose propellent, wherein said [propellent] propellant coupler has at least one aperture which communicates between said interior volume of said conformable dose sequestration element and said fluid dose [propellent] propellant.
119. An intranasal delivery device as described in claim 118, wherein said first end of said [propellent] propellant coupler comprises an annular barb engaged to said interior surface of said conformable dose sequestration element.
120. An intranasal delivery device as described in claim 119, wherein said second end of said [propellent] propellant coupler comprises a syringe adaptor.
121. An intranasal delivery device as described in claim 120, wherein said syringe

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adaptor comprises a luer-lock.

122. An intranasal delivery device as described in claim 121, wherein said [propellent] propellant coupler, and said dose-location coordinate indicator comprise unitized construction.
123. An intranasal delivery device as described in claim 122, wherein said force application element is a syringe.
124. An equine intranasal delivery device as described in claim 123, wherein said dose comprises a substance selected from the group consisting of: a composition, a therapeutic composition, a prophylactic composition, a drug, a protein, a nucleic acid, an immunogen, an immunogen which elicits an immune response, a live virus, a reassortant live virus, a cold-adapted live virus, an attenuated live virus, an equine cold-adapted live influenza virus which replicates in embryonated chicken eggs within a temperature range from about 26EC to about 30EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 37EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 39EC, a equine cold-adapted live virus having a phenotype wherein protein synthesis is inhibited above about 39EC, an equine cold-adapted live virus having a dominant interference phenotype, an equine influenza cold-adapted live virus derived from strain A/equine/ Kentucky/1/91 (H3N8), EIV-P821(identified by accession No. ATCC VR 2625), EIV-P824 (identified by accession No. ATCC VR 2624), MSV+5 (identified by accession No. 2627), any progeny of any of said equine influenza viruses identified by such accession Nos., any EIV having the identifying characteristics of said ATCC VR strains, or an equine influenza cold adapted live virus having about  $10^5$  TCID<sub>50</sub> to about  $10^8$  TCID<sub>50</sub> units.
125. An intranasal delivery device as described in claim 124, further comprising an equid.

126. A method of delivering a dose intranasally, comprising the steps of:
- a. sequestering a dose within an dose sequestration element, wherein said [conformable] dose sequestration element separates said dose from a force application element with a volume of a fluid dose [propellent] propellant;
  - b. measuring a volume of fluid dose [propellent] propellant, wherein said volume is in excess of a minimum delivery volume of said dose;
  - c. applying force to said volume of said fluid dose [propellent] propellant;
  - d. propelling said dose from said interior volume of said dose sequestration element;
  - e. delivering said dose to a target susceptible to said dose; and
  - f. expelling a remaining portion of said volume of said fluid dose [propellent] propellant from said conformable dose sequestration element.
127. A method of intranasal delivery as described in claim 126, wherein said step of delivering said dose to said target susceptible to said dose comprises streaming said dose onto said target susceptible to said dose.
128. A method of intranasal delivery as described in claim 127, wherein said step of sequestering said dose within said interior volume of said dose sequestration element further comprises:
- a. establishing at least one dose in a volume of diluent;
  - b. submerging said dose sequestration element into said volume of solvent containing said at least one dose; and
  - c. reducing pressure within said volume of said conformable dose sequestration element sufficiently to transfer said dose into said interior volume of said conformable dose sequestration element.
129. A method of intranasal delivery as described in claim 128, wherein establishing said at least one dose within said volume of said conformable dose sequestration element further comprises retaining said dose in a position by capillary forces.

130. A method of intranasal delivery as described in claim 129, further comprising the step of providing an intranasal probe responsive to said conformable dose sequestration element.
131. A method of intranasal delivery as described in claim 130, further comprising the step of providing a flexible dose administrator responsive to said conformable dose sequestration element.
132. A method of intranasal delivery as described in claim 131, further comprising the step of sliding said intranasal probe up a nostril of an animal.
133. A method of intranasal delivery as described in claim 132, further comprising the step of guiding said intranasal probe so as to not enter an opening to a false nostril.
134. A method of intranasal delivery as described in claim 133, further comprising the step of positioning a dose-location coordinate indicator into proximity with an exterior portion of said nostril of said animal.
135. A method of intranasal delivery as described in claim 134, wherein said step of positioning a dose-location coordinate indicator into proximity with an exterior portion of said nostril of said equid assures a dose-location coordinate having a temperature of about 26EC to about 34EC
136. A method of intranasal delivery as described in claim 135, further comprising the step of terminating sliding of said intranasal probe up said nostril of said animal.
137. A method of intranasal delivery as described in claim 136, further comprising the step of administering said dose to said target of an equid.
138. An equine intranasal delivery device as described in claim 137, further comprising the step of selecting said from the group consisting of: a composition, a therapeutic

composition, a prophylactic composition, a drug, a protein, a nucleic acid, an immunogen, an immunogen which elicits an immune response, a live virus, a reassortant live virus, a cold-adapted live virus, an attenuated live virus, an equine cold-adapted live influenza virus which replicates in embryonated chicken eggs within a temperature range from about 26EC to about 30EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 37EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 39EC, a equine cold-adapted live virus having a phenotype wherein protein synthesis is inhibited above about 39EC, an equine cold-adapted live virus having a dominant interference phenotype, an equine influenza cold-adapted live virus derived from strain A/equine/ Kentucky/1/91 (H3N8), EIV-P821 (identified by accession No. ATCC VR2625), EIV-P824 (identified by accession No. ATCC VR2526), MSV+5 (identified by accession No.2627), any progeny of any of said equine influenza viruses identified by such accession Nos., any EIV having the identifying characteristics of said ATCC VR strains, or an equine influenza cold adapted live virus having about  $10^5$  TCID<sub>50</sub> to about  $10^8$  TCID<sub>50</sub> units.

139. An intranasal dose delivery device, comprising:
  - a. a stream delivery element;
  - b. a dose delivery aperture element coupled to said stream delivery element;
  - c. an intranasal probe responsive to said dose delivery aperture;
  - d. a flexible dose administrator;
  - e. an intranasal probe coupler having a first end responsive to said intranasal probe and a second end responsive to said flexible dose administrator, wherein said intranasal probe coupler has at least one aperture which communicates between said intranasal probe and said stream delivery element;
  - f. a force application element responsive to said flexible dose administrator; and
  - g. a force application element coupler having a first end responsive to said

flexible dose administrator and a second end responsive to said force application element, wherein said force application coupler has at least one aperture which communicates between said flexible dose administration element and said force application element.

140. An intranasal delivery device as described in claim 139, wherein said stream delivery element has an aperture having a diameter of about 0.75 millimeters (about 0.030 inches).
141. An intranasal delivery device as described in claim 140, wherein said flexible dose administrator has a cylindrical exterior surface.
142. An intranasal delivery device as described in claim 141, wherein said cylindrical exterior surface has a diameter of about 6 millimeters (about 0.250 inches).
143. An intranasal delivery device as described in claim 142, wherein said cylindrical exterior surface has a length of about 150 millimeters (about 5.9 inches).
144. An intranasal delivery device as described in claim 143, further comprising a force dissemination contact surface having hebetated termini coupled to said intranasal probe.
145. An intranasal delivery device as described in claim 144, wherein said force dissemination contact surface responsive to said flexible intranasal probe comprises a sphere cap, wherein said sphere cap and said cylindrical exterior surface of said flexible dose administrator form a contiguous surface.
146. An intranasal delivery device as described in claim 145, wherein said sphere cap has a radius of about 3 millimeters (about 0.125 inches) and a sphere cap height of about 1 millimeters (about 0.040 inches).
147. An intranasal delivery device as described in claim 146, wherein said intranasal

probe and said force dissemination contact surface have a unitized construction.

148. An intranasal delivery device as described in [any one of] claim[s] 139 [or 146], further comprising a conformable dose sequestration element having a dose sequestration volume responsive to said flexible dose administrator.
149. An intranasal delivery device as described in claim 148, wherein said conformable dose sequestration element further comprises a dose retainer, wherein said dose retainer has a location proximate to said stream delivery element.
150. An intranasal delivery device as described in claim 149, wherein said dose retainer comprises a capillary.
151. An intranasal delivery device as described in claim 150, wherein said capillary has a diameter of 3 millimeters (about 0.125 inches).
152. An intranasal delivery device as described in claim 151, further comprising an axial collapse prevention element coupled to said flexible dose administrator.
153. An intranasal delivery device as described in claim 152, wherein said axial collapse prevention element comprises a resiliently flexible layer between said cylindrical exterior surface of said flexible dose administrator and said conformable dose sequestration element.
154. An intranasal delivery device as described in claim 153, wherein said resiliently flexible layer comprises polyvinyl chloride having a thickness of about 1.5 millimeters (0.040 inches).
155. An intranasal delivery device as described in claim 154, further comprising a dose-location coordinate indicator coupled to said flexible dose administrator.

156. An intranasal delivery device as described in claim 155, wherein said dose-location coordinate indicator comprises a visually enhanced surface.
157. An intranasal delivery device as described in claim 156, wherein said visually enhanced surface comprises an annular projection.
158. An equine intranasal delivery device as described in claim 157, wherein said dose-location coordinate indicator has a position which assures a dose-location coordinate temperature between about 26<sup>N</sup> C to about 34<sup>N</sup> C.
159. An intranasal delivery device as described in claim 158, wherein said dose-location coordinate indicator has a position on said flexible intranasal probe distal from said stream delivery element of about 150 millimeters (about 5.9 inches).
160. An intranasal delivery device as described in claim 159, further comprising a fluid dose [propellant] propellant which separates said conformable dose sequestration element from said force application element.
161. An intranasal delivery device as described in claim 160, wherein said flexible dose administrator and said dose sequestration element have a unitized construction.
162. An intranasal delivery device as described in claim 161, wherein said second end of said intranasal probe coupler comprises an annular barb engaged to said interior surface of said flexible dose administrator.
163. An intranasal delivery device as described in claim 162, wherein said intranasal probe coupler and intranasal probe comprise unitized construction.
164. An intranasal delivery device as described in claim 163, wherein said intranasal probe coupler, said intranasal probe, and said force dissemination contact surface having hebetated termini comprise unitized construction.

165. An intranasal delivery device as described in claim 164, wherein said first end of said [propellent] propellant coupler comprises an annular barb engaged to said interior surface of said flexible dose administrator.
166. An intranasal delivery device as described in claim 165, wherein said second end of said force application element coupler comprises a syringe adaptor.
167. An intranasal delivery device as described in claim 166, wherein said syringe adaptor comprises a leur-lock.
168. An intranasal delivery device as described in claim 167, wherein said force application element coupler and said dose-location coordinate indicator comprise unitized construction.
169. An intranasal delivery device as described in claim 168, further comprising a dose responsive to said stream delivery element.
170. An equine intranasal delivery device as described in claim 169, wherein said dose comprises a substance selected from the group consisting of: a composition, a therapeutic composition, a prophylactic composition, a drug, a protein, a nucleic acid, an immunogen, an immunogen which elicits an immune response, a live virus, a reassortant live virus, a cold-adapted live virus, an attenuated live virus, an equine cold-adapted live influenza virus which replicates in embryonated chicken eggs within a temperature range from about 26EC to about 30EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 37EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 39EC, a equine cold-adapted live virus having a phenotype wherein protein synthesis is inhibited above about 39EC, an equine cold-adapted live virus having a dominant interference phenotype, an equine influenza cold-adapted live virus derived from



strain A/equine/ Kentucky/1/91 (H3N8), EIV-P821(identified by accession No. ATCC VR 2625), EIV-P824 (identified by accession No. ATCC VR 2624), MSV+5 (identified by accession No.2627), any progeny of any of said equine influenza viruses identified by such accession Nos., any EIV having the identifying characteristics of said ATCC VR strains, or an equine influenza cold adapted live virus having about  $10^5$  TCID<sub>50</sub> to about  $10^8$  TCID<sub>50</sub> units.

171. An intranasal delivery device as described in claim 170, further comprising a volume of diluent, wherein said volume of diluent and said dose are combined.
172. An intranasal delivery device as described in claim 171, further comprising an equid.
173. A method of delivering a dose intranasally, comprising the steps of:
- a. establishing a dose in a volume of diluent within a flexible administrator;
  - b. positioning said flexible administrator within a nostril of an animal;
  - c. applying force to said dose in said volume of diluent;
  - d. propelling said dose in said volume of diluent from a stream delivery element; and
  - e. streaming said dose in said volume of diluent onto a target susceptible to said dose.
174. A method of delivering a dose intranasally as described in claim 173, wherein steps d and e occur simultaneously.
175. A method of delivering a dose intranasally as described in claim 174, further comprising the step of providing a flexible dose administrator responsive to said intranasal probe.
176. A method of delivering a dose intranasally as described in claim 175, further comprising the step of sliding said flexible dose administrator up a nostril of an animal.

177. A method of delivering a dose intranasally as described in claim 176, further comprising the step of disseminating the force of contact between said flexible dose administrator and a nasal passage of said animal.
178. A method of delivering a dose intranasally as described in claim 177, further comprising the step of preventing axial collapse of said flexible dose administrator.
179. A method of delivering a dose intranasally as described in claim 178, further comprising the step of positioning a dose-location coordinate indicator into proximity with an exterior portion of said nostril of said animal.
180. A method of intranasal delivery as described in claim 179, wherein said step of positioning a dose-location coordinate indicator into proximity with an exterior portion of said nostril of said equid assures a dose-location coordinate having a temperature of about 26EC to about 34EC
181. A method of delivering a dose intranasally as described in claim 180, further comprising the step of terminating sliding of said flexible dose administrator up said nostril of said animal.
182. A method of delivering a dose intranasally as described in claim 181, further comprising the step of sequestering a dose in a volume of a conformable dose sequestration element, wherein said conformable dose sequestration element separates said dose from a force application element with a volume of fluid dose [propellant] propellant.
183. A method of delivering a dose intranasally as described in claim 182, further comprising the step of measuring a volume of fluid dose [propellant] propellant, wherein said volume of fluid dose [propellant] propellant has a volume in excess of a minimum dose delivery volume.

184. A method of delivering a dose intranasally as described in claim 183, further comprising chasing said dose with said volume in excess of said minimum dose delivery volume.
185. A method of intranasal delivery as described in claim 184, wherein said step of sequestering said dose within said interior volume of said dose sequestration element further comprises:
- establishing at least one dose in a volume of diluent;
  - submerging said conformable dose sequestration element into said volume of diluent containing said at least one dose; and
  - reducing pressure within said volume of said conformable dose sequestration element sufficiently to transfer said dose into said dose sequestration volume of said conformable dose sequestration element.
186. A method of intranasal delivery as described in claim 185, wherein establishing said at least one dose within said volume of said conformable dose sequestration element further comprises retaining said dose in a position proximate to said stream delivery element by capillary forces.
187. A method of intranasal delivery as described in claim 186, further comprising the step of administering said dose to an equid.
188. A method of intranasal delivery as described in claim 187, further comprising the step of guiding said flexible dose administrator so as to not enter an opening to a false nostril.
189. An equine intranasal delivery device as described in claim 188, wherein said dose comprises a substance selected from the group consisting of: a composition, a therapeutic composition, a prophylactic composition, a drug, a protein, a nucleic acid, an immunogen, an immunogen which elicits an immune response, a live virus,

a reassortant live virus, a cold-adapted live virus, an attenuated live virus, an equine cold-adapted live influenza virus which replicates in embryonated chicken eggs within a temperature range from about 26EC to about 30EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 37EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 39EC, a equine cold-adapted live virus having a phenotype wherein protein synthesis is inhibited above about 39EC, an equine cold-adapted live virus having a dominant interference phenotype, an equine influenza cold-adapted live virus derived from strain A/equine/ Kentucky/1/91 (H3N8), EIV-P821(identified by accession No. ATCC VR 2625), EIV-P824 (identified by accession No. ATCC VR 2624), MSV+5 (identified by accession No.2627), any progeny of any of said equine influenza viruses identified by such accession Nos., any EIV having the identifying characteristics of said ATCC VR strains, or an equine influenza cold adapted live virus having about  $10^5$  TCID<sub>50</sub> to about  $10^8$  TCID<sub>50</sub> units.

190. An intranasal delivery device, comprising:
- [b. an intranasal probe coupled to said dose administrator;]
  - a. a [flexible] dose administrator having a volume;
  - b. an intranasal probe coupled to said dose administrator;
  - c. an intranasal probe coupler having a first end responsive to said intranasal probe and a second end responsive to said dose administrator, wherein said intranasal probe coupler has at least one aperture which communicates between said volume of said dose administrator and an exterior surface of said intranasal probe;
  - d. a force application element coupled to said dose administrator;
  - e. a coupler element having a first end responsive to said dose administrator and a second end responsive to said force application element, wherein said coupler element has at least one aperture which communicates between [a] said volume of said dose administrator and said force application element;
  - f. a dose-location coordinate indicator responsive to said [flexible] dose

administrator; and  
g.[.] a dose[;].

191. An intranasal delivery device as described in claim 190, further comprising a force dissemination contact surface having hebetated termini responsive to said exterior surface of said intranasal probe.
192. An intranasal delivery device as described in claim 191, further comprising a fluid dose [propellent] propellant which separates said dose from said force application element.
193. An intranasal delivery device as described in claim 192, further comprising a conformable dose sequestration element having a sequestration volume sufficient to sequester said dose, wherein said sequestration volume communicates with said dose delivery aperture element and said fluid dose [propellent] propellant.
194. An intranasal delivery device as described in claim 193, wherein said fluid dose propellent has a greater volume than a minimum dose delivery volume.
195. An intranasal delivery device as described in claim 194, wherein said conformable dose sequestration element further comprises a dose retainer, wherein said dose retainer positions said dose proximate to said dose delivery aperture.
196. An intranasal delivery device as described in claim 195, further comprising a stream delivery element coupled to said dose delivery aperture.
197. An intranasal delivery device as described in claim 196, wherein said dose comprises a substance selected from the group consisting of: a composition, a therapeutic composition, a prophylactic composition, a drug, an immunogen, an immunogen which elicits an immune response, a protein, a nucleic acid, a live virus, or a reassortant live virus.

198. An equine intranasal delivery device as described in claim 197, wherein said dose-location coordinate indicator has a position which assures a dose-location coordinate temperature between about 26<sup>N</sup> C to about 34<sup>N</sup> C.
199. An intranasal delivery device as described in claim 198, wherein said dose comprises a substance selected from the group consisting of: a live virus, a reassortant live virus, a cold-adapted live virus, an attenuated live virus, an equine cold-adapted live influenza virus which replicates in embryonated chicken eggs within a temperature range from about 26EC to about 30EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 37EC, an equine influenza cold-adapted live virus which does not form plaques in tissue culture cells at a temperature above about 39EC, an equine cold-adapted live virus having a phenotype wherein protein synthesis is inhibited above about 39EC, an equine cold-adapted live virus having a dominant interference phenotype, an equine influenza cold-adapted live virus derived from strain A/equine/ Kentucky/1/91 (H3N8), EIV-P821 (identified by accession No. ATCC VR 2625), EIV-P824 (identified by accession No. ATCC VR 2624), MSV+5 (identified by accession No. 2627), any progeny of any of said equine influenza viruses identified by such accession Nos., any EIV having the identifying characteristics of said ATCC VR strains, or an equine influenza cold adapted live virus having about 10<sup>5</sup> TCID<sub>50</sub> to about 10<sup>8</sup> TCID<sub>50</sub> units.
200. An intranasal delivery device as described in claim 199, further comprising a dose diluent, wherein said dose and said dose diluent are combined.

Claims 201 and 202 canceled without prejudice.

## CONCLUSION

Claims 1-41 and 201-202 have been cancelled without prejudice. Claims 42-200 remain in the application. Each of claims 42-200 satisfy the criteria of PCT Article 33(1)-(4), have unity of invention, and have only been amended to the extent necessary to eliminate objections as to form or to cancel rejected claims. The applicant having satisfied the requirements of 37 C.F. R. §1.496(b), and unity of invention, respectfully requests that the application be taken out of order and that claims 42-200 be examined as a single group.

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Respectfully Submitted,

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